PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03019WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/DK2004/000223	International filing date *(day/month/year)* 31.03.2004	Priority date *(day/month/year)* 01.04.2003
International Patent Classification (IPC) or national classification and IPC A61N1/36		
Applicant JADIDI, Faramarz		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.02.2005	01.04.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Wetzig, T Telephone No. +49 89 2399-7412

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000223

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-44	as originally filed
Claims, Numbers	
1-28	received on 03.02.2005 with letter of 01.02.2005
Drawings, Sheets	
1/20-20/20	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000223

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 26-28

because:

☒ the said international application, or the said claims Nos. 26-28 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 26-28

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industri applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-25
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-25
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III

Claims 26-28 refer to a therapeutic treatment due to the preventive treatment of bruxism and the correction of human body positioning and/or movements. Therefore, the IPEA is not required to carry out an examination on these claims (Cf. Rule 67.1(iv) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1: US-A-5 368 043
D2: US-A-4 967 761

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claims 1, 22, 24 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses:
An apparatus for monitoring muscle activity (see D1, abstract), said apparatus comprising
- means for providing signals indicative of muscle activity, for example EMG signals (see D1, figure 1 (1A..N), col. 4, lines 36-50),
- means for processing of said signals in order to detect a particular undesired activity (see D1, col. 2, line 61 - col. 3, line 7, col. 3, lines 32-46, col. 6, lines 48-55 (The detected imbalance in the activity of the pair of left and right muscles represents a particular undesired activity.)),
- means for providing a biofeedback signal (see D1, figure 1 (22), col. 3, lines 8-20 (A feedback signal provided to person by means of a display represents a biofeedback signal.))
wherein
- said apparatus is designed in order to be operated in a set-up mode and a use-mode (see D1, col. 3, lines 21-31)
- said apparatus is designed to be individually adaptable in said set-up mode, wherein a normally occurring muscle activity and an essentially maximal muscle activity is

registered (see D1, col. 3, lines 8-31), and wherein
- said means for processing of said signals in order to detect a particular undesired activity is adapted to perform an evaluation based on the amplitude of the signals registered in said use-mode compared with corresponding values registered in said set-up mode (col. 3, lines 32-46).

The subject-matter of claim 1 therefore differs in that the signal evaluation is additionally based on the **frequency** of the signals.

The problem to be solved by the present invention may therefore be regarded as to find an alternative solution for muscle signal evaluation in order to detect a particular undesired activity.

The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
The evaluation of muscle signals based on the frequency of the signals in order to detect a particular undesired activity is known from document D2 (see D2, abstract (Preterm labor is an undesired activity.)).

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent method claims 22, 24, which therefore are also considered not inventive.

Dependent claims 2-21, 23, 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see the documents and the corresponding passages cited in the search report.

Amended Patent Claims

1. Apparatus for monitoring muscle activity, said apparatus comprising

- means for providing signals indicative of muscle activity, for example EMG-signals,
- means for processing of said signals in order to detect a particular undesired activity,
- means for providing a biofeedback signal,

wherein

- said apparatus is designed in order to be operated in a set-up mode and a use-mode,
- said apparatus is designed to be individually adaptable in said set-up mode, wherein a normally occurring muscle activity and an essentially maximal muscle activity is registered, and wherein
- said means for processing of said signals in order to detect a particular undesired activity is adapted to perform an evaluation based on frequency and amplitude of the signals registered in said use-mode compared with corresponding values registered in said set-up mode.

2. Apparatus according to claim 1, c h a r a c t e r i z e d i n that said means for processing of said signals in order to detect a particular activity comprises means for performing a FFT (Fast Fourier Transform) analysis.

3. Apparatus according to claim 1 or 2, c h a r a c t e r i z e d i n that said apparatus is adapted to register a reference amplitude value corresponding to a percentage of said essentially maximal muscle activity registered in said set-up mode, said reference amplitude value being used for said evaluation.

4. Apparatus according to claim 1, 2 or 3, c h a r a c t e r i z e d i n that said means for processing of said signals in order to detect a particular undesired activity is further adapted to perform an evaluation based on an area calculation of the signals

registered in said use-mode, i.e. based on a signal continuously exceeding a predefined value such as said reference amplitude value.

5. Apparatus according to one or more of claims 1 to 4, characterized in that said essentially maximal muscle activity is a maximal jaw clenching activity.

6. Apparatus according to one or more of claims 1 to 5, characterized in that said apparatus is designed for sensing and registering muscle activity during one or more predefined normally occurring muscle activities, such as one or more grimaces.

7. Apparatus according to one or more of claims 1 to 6, characterized in that said apparatus comprises means for registering and storing muscle activity during a time interval.

8. Apparatus according to one or more of claims 1 to 7, characterized in that said apparatus is designed to be individually adaptable by having means for adjusting said feedback signal.

9. Apparatus according to one or more of claims 1 to 8, characterized in that said means for processing of said signals in order to detect a particular activity comprises means for pattern recognition.

10. Apparatus according to one or more of claims 1 to 9, characterized in that said means for providing signals indicative of muscle activity comprises one or more electrodes for sensing of EMG-signals.

11. Apparatus according to one or more of claims 1 to 10, characterized in that said means for providing signals indicative of muscle activity comprises one or more electrodes for sensing of EEG-signals.

12. Apparatus according to claim 10 or 11, characterized in that said device comprises means for testing said electrodes and in particular the connectivity to the user by supplying a test voltage to the electrode(s), possibly as a superimposed voltage, measuring the resulting current and comparing the resulting current with reference value(s).

13. Apparatus according to one or more of claims 1 to 12, characterized in that said means for providing signals indicative of muscle activity comprises a microphone, a sensor for sensing of vibrations and/or other sensor means.

14. Apparatus according to one or more of claims 1 to 13, characterized in that said apparatus comprises means for storing data corresponding to measured and/or processed signals.

15. Apparatus according to claim 14, characterized in that the apparatus comprises means for transferring stored data to a computer, e.g. a PC or the like.

16. Apparatus according to one or more of claims 1 to 15, characterized in that in said set-up mode individual reference signals, signals corresponding to specific individual muscle activities and individual bio-feedback signal characteristics may be set-up, and that in said user mode the device may monitor muscle activity and provide bio-feedback in accordance with predefined rules and settings.

17. Apparatus according to one or more of claims 1 to 16, characterized in that the apparatus comprises a user module for wearing on the head, e.g. on the forehead, on or in the ear, etc.

18. Apparatus according to one or more of claims 1 to 17, characterized in that the apparatus comprises a slave module and a master module, said slave module being designed for wearing by a human being.

19. Apparatus according to one or more of claims 1 to 18, characterized in that said apparatus comprises charging means, e.g. for said user module or for said slave module.

20. Apparatus according to claim 17, 18 or 19, characterized in that said apparatus comprises means for indicating operating steps to a user such as visual means, e.g. a LED, or acoustic means.

21. Apparatus according to one or more of claims 17 to 20, characterized in that said apparatus comprises display means for displaying instructions and/or results stemming from a monitoring session.

22. Method of monitoring muscle activity, said method comprising the steps of

- providing signals indicative of muscle activity, for example EMG-signals,
- registering of reference signals corresponding to a normally occurring muscle activity and an essentially maximal muscle activity in a set-up step,
- processing of signals indicative of muscle activity in a use step in order to detect a particular undesired activity, said processing of said signals taking into consideration specific individual parameters and/or references including frequency and amplitude of the reference signals registered in said set-up step, and
- providing a feedback signal in case a particular undesired activity has been detected.

23. Method according to claim 22, characterized in that said feedback is provided on the basis of an evaluation comprising a maximum force calculation, an area calculation and/or a pattern recognition process on the basis of a FFT-processing (Fast Fourier Transform).

24. Method of setting up an apparatus according to one or more of claims 1 to 21, whereby

- an essentially maximal muscle activity such as a maximal jaw clenching is performed and the corresponding muscle activity signal is sensed and registered as regards frequency and amplitude,
- one or more predefined muscle activities is/are performed, e.g. grimaces, and the corresponding muscle activity signal is sensed and registered as regards frequency and amplitude, and
- a threshold value for outputting of a feedback-signal is adjusted.

25. Method of setting up an apparatus according to one or more of claims 1 to 21, possibly subsequent to a setting-up procedure in accordance with claim 24, whereby
- said method comprises the steps of using the apparatus in a set-up mode, whereby values and/or parameters corresponding to individual muscle activities are registered and possibly stored for one or more periods of time, and
- whereby said registered and/or stored values and/or parameters are utilized for providing individual reference values for normal use of the apparatus.

26. Use of apparatus according to one or more of claims 1 to 21 and/or a method according to one or more of claims 22 – 25 for preventive treatment of bruxism.

27. Use of apparatus according to one or more of claims 1 to 21 and/or method according to one or more of claims 22 – 25 for corrective monitoring of human body positioning and/or movements.

28. Use of apparatus according to one or more of claims 1 to 21 and/or method according to one or more of claims 22 – 25 for adjusting of human body positioning and/or movements during work activity.